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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/755,830	01/05/2001	Katia Georgopoulos	10287-067001	5392

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EXAMINER	
WOITACH, JOSEPH T	
ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.	Applicant(s)
09/755,830	Georgopoulos
Examiner	**Art Unit**
Joseph Woitach	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 25, 2003*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above, claim(s) *11-50* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Jan 5, 2001* is/are a) ☒ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

This application is a continuation-in-part of 08/283,300, filed July 29, 1994, now US Patent 6,172,278, which is a continuation-in-part of 08/238,212, filed May 2, 1994, now abandoned, and continuation-in-part of 08/121,438, filed September 14, 1993, now abandoned, and continuation-in-part of 07/946,233, filed September 14, 1992, now abandoned.

Election/Restriction

Claims 1-50 are pending. Claims 11-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 15. Claims 1-10 are currently under examination.

Information Disclosure Statement

The information disclosure statement filed January 7, 2002, paper number 7, and October 15, 2002, paper number 12, comply with 37 CFR 1.98(a)(2). With regard to the information disclosure January 7, 2002, paper number 7, each of the references listed have been provided in the parent applications have been reviewed. A signed and initialed copy of the 1448 forms are included with this action.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

In the instant case, the specific Ikaros transcriptional/promoter sequences instantly claimed are first presented in the instant application. Previous applications are silent with respect to teachings which would support the instantly product, and thus fail to fully support the elected invention under 35 U.S.C. 112, first paragraph. Accordingly, the priority date given the pending claims is the filing date of the instant application.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The final Written Description Examination guidelines that were published on January 5, 2001 (66 FR 1099; available at http://www.uspto.gov/web/menu/current.html).

Claim 1 is directed to an Ikaros transcriptional control region comprising one or mor Ikaros regulatory elements. Dependent claims recite specific promoter clusters comprised in the control region (claims 2-6) and operative linkage of the Ikaros transcriptional control region to a reporter gene (claims 7-10). The basis of the instant rejection focuses on the failure of the instant disclosure to provide adequate written description of an Ikaros transcriptional control region which is encompassed by the claim. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

In the instant case, the specification teaches that a genomic clone of the Ikaros gene has been isolated and the 5' end of said clone has been analyzed. DNAaseI hypersensitive sites (HHS) are described and asserted to represent specific control regions of the Ikaros gene (see summary in figure 9). By analyzing cells of several different types by HHS, the disclosure

teaches that the Ikaros gene may have two possible different promoters, and that the "putative promoters are associated with two distinct clusters of lymphoid-specific DNaseI HHS" (page 79, lines 25-30). The specification and the art of record is silent with respect to any specific sequence regarded as an Ikaros transcriptional control region or any teaching of what transcriptional factors are implicated in the control of the Ikaros transcriptional control region comprised on the large genomic clone. The only specific teaching for potentially important cluster regions of the genomic clone is the HHS analysis of various cell types. Again, the specification is silent with respect to any specific sequence for the Ikaros transcriptional control region, and it fails to provide any specific guidance to what transcriptional factors bind or regulate the Ikaros gene or the specific control region instantly claimed. Moreover, the specification is silent with respect to what would be defined as transcriptional control region. Besides the implication of particular regions of the genomic clone by HHS analysis in specific cell types, there is no specific functional attributes described in the specification which would be considered indicative of an Ikaros regulatory element. Further, there is no specific definition of a control region being active or inactive in any particular context which clearly defines an assay to test whether a specific sequence is a or part of a Ikaros transcriptional regulatory region. It is noted that the specification sets forth the particular terms and embodiments recited in the claims, however the specification fails to provide any specific sequence or the necessary guidance to what the specific sequences comprised by the terms. The claims are broad encompassing an enormous number of species of Ikaros transcriptional control region from any species of

organism. Further, the claims include fragments and specific clusters which have no specific defined activity. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants effective filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. *Pfaff v. Wells Electronics, Inc.,* 48 USPQ2d 1641, 1646 (1998). In the instant case, the specification provides literal support for the recited embodiments, however the specification fails to describe the relevant identifying characteristics of any of the nucleic acid sequences of any of the sequences encompassed by the claims. The portions of the specification discussed above are noted, however written description requires more than a mere indication of "putative promoters" (page 79, line 27). Again, no specific sequence is taught in the specification nor the art of record. There is no evidence that these specific clusters observed by HHS analysis in one genomic clone are important to function or whether any alteration will result in a modification of activity, or if they are consistent with genomic sequences obtained from the same region of Ikaros of different species of animals. Absent any specific teaching of any sequence the skilled artisan can not envision all the possible variant nucleic acid sequences which are comprised by the instant claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity

or simplicity of the method used. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of identifying it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

Applicants attention is drawn to the decision of *The Regents of the University of California v. Eli Lilly and Company* (CAFC, July 1997) wherein it was stated:

In claims involving chemical materials, generic formulas usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate written description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian cDNA," without more, is not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See *Fiers,* 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen*). It is only a definition of a useful result rather than a definition of what it achieves as a result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. *See In re Wilder*, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. In the instant case, Examiner would not contest that the Ikaros gene has a transcriptional control region, however in view of the teachings of the instant specification it is maintained that the artisan would not be

able to distinguish any particular sequence as an Ikaros transcriptional control region. Further, even if a given sequence could be tested, no specific biological activity of the Ikaros control region or of any of the specific clusters has been clearly set forth to assay.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. In the instant case, the specification fails to describe even a single species of each enormous genus comprised by the claims, and because one of skill in the art could not be expected to predict the biological activity of the sequence variants encompassed by the claims, the written description requirement has not been met.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kaufmann *et al.* (EMBO, 22(9):2211-2223, 2003) is a post filing reference providing essentially the same information disclosed in the instant disclosure about the regulatory region of the Ikaros gene. Kaufmann *et al.* conclude that the studies presented provide the foundation for the regulation of Ikaros expression, however that the promoter is complex and that further delineation of the regulatory elements of Ikaros are needed to gain insight into the molecular mechanisms and role of Ikaros (page 2221, second column).

Conclusion

No claim is allowed. The claims are free of the art of record because the art fails to teach or make obvious the regulatory region of the Ikaros gene, however the clams are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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